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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|----------------|----------------------|---------------------|------------------|
| 09/852,447 | 05/09/2001 | Gary E. Ross | 3125.00003 | 5137 |
| 7: | 590 02/24/2005 | | EXAM | INER |
| Kenneth I. Kohn | | | HILLERY, NATHAN | |
| Kohn & Associ | ates | | | |
| 30500 Northwestern Hwy., Suite 410 | | | ART UNIT | PAPER NUMBER |
| Farmington Hills, MI 48334 | | | 2176 | |

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|--|---|---------------|--|--|--|
| Office Action Summary | | 09/852,447 | ROSS, GARY E. | | | |
| | | Examiner | Art Unit | | | |
| <u>.</u> | | Nathan Hillery | 2176 | | | |
| | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 15 October 2004. | | | | | |
| 2a) <u></u> ☐ | This action is <i>FINAL</i> . 2b)⊠ Th | nis action is non-final. | | | | |
| 3)□ | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4) Claim(s) 1-26 and 51 is/are pending in the application. 4a) Of the above claim(s) 27-50 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-26 and 51 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicati | ion Papers | | | | | |
| | The specification is objected to by the Exami The drawing(s) filed on [4](d) is/are: a) [X] a | | Examiner. | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) Notice 3) Infor | et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 er No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other: | | | | |

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DETAILED ACTION

1. This action is responsive to communications: Restriction Election filed on 10/15/04.

Claims 1 – 26 and 51 are pending in the case as a result of an Election by
 Applicant. Claims 1, 15 and 51 are independent.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 – 26 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1 – 14 amounts functional descriptive data. Because the claims are means plus function, the claimed invention is considered software per se. The rejection to these claims may be overcome if an inference to some form of hardware is claimed. Claims 15 – 26 refer to software per se and recite a system that is not tangibly embodied to a computer system. Claim 51 can reflect a series of mental/manual steps. The claimed invention simply manipulates abstract ideas without practical application in the technological arts. Consequently, the claimed invention(s) do not require the technical or useful arts and, thus, fail to define patentable subject matter.

7. Further, to expedite a complete examination of the instant application the claims rejected under 35 U.S.C. 101 (nonstatutory) above are further rejected as set forth below in anticipation of applicant amending these claims to place them within the four statutory categories of invention.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 5. Claims 1, 3-4, 6-9, 15-17, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
- 6. Claims 1, 3 4, 6 9, 15 17, and 19 21 are single means claim(s), i.e., where a means recitation does not appear in combination with another recited element of means. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983). See MPEP § 2164.08(a).
- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 1 26 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. Regarding independent claims 1, 15 and 51, it is unclear what applicant means by "eliciting more accurate conclusions". The metes and bounds of the claim are unclear. Consequently, all subsequent recitations of "eliciting more accurate conclusions" are also rejected.

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10. Regarding independent claims 1, 15, and 51, "more accurate conclusions" lacks comparative basis. Consequently, all subsequent recitations of "more accurate conclusions" are also rejected.

- 11. Claims 7, 9, and 16 contain improper Markush group language, i.e. the metes and bounds of "consisting essentially of" are unclear.
- 12. Regarding dependent claims 2 14 and 16 26, the claims are rejected for incorporating the deficiencies of the base claim(s) from which they depend.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 14. Claims 1 26 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Iliff (US 5660176 A).
- 15. Regarding independent claim 1, lliff teaches that in situations where the MDATA system 100 cannot determine with sufficient certainty what is causing a particular problem (no diagnosis) or in a situation where a diagnosis is available but additional information is desirable, e.g., to determine a trend, a re-enter flag may be set by the system 100. At a decision state 520, the computer 102 determines if re-enter criteria are met for the current algorithm and patient situation. If so, the computer sets

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the re-enter flag at state 522 for this problem so a subsequent telephone consultation by the patient will allow for additional information to be added to the patient record by the system in full knowledge of the previous call. This additional information may yield a better diagnosis (Column 42, lines 21 – 34), which provide a documentation system comprising augmenting means for eliciting more accurate conclusions through the analysis of entered information and predetermined criteria input.

- 16. Regarding dependent claim 2, Hiff teach that a patient response database, having a trace response file for each patient, stored in the computer, wherein the patient response database is created by the evaluation process, a patient medical history database stored in the computer having a past medical history file for each patient, wherein the patient medical history database is created (Column 4, line 63 Column 5, line 2), which provide storage means for recording inputted predetermined criteria, entered information and conclusions thereof into a database.
- 17. **Regarding dependent claim 3**, lliff teaches that as another embodiment of the MDATA system, a person desiring medical advice and having access to a personal computer (PC) loads a program into the PC to produce a stand-alone medical diagnostic and treatment advice (SA-MDATA) system (Column 4, lines 18 22), which provide a software program encoding for said augmenting means.
- 18. **Regarding dependent claim 4**, Iliff teaches that the algorithm processor 160 loads node #101, represented by node block 214. The work list is empty, so the system 100 goes right to playing back message#101 which presents another menu of choices to the user. The Next list has four nodes for possible branch points. In this example,

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the patient selects menu option "1" for a chest pain complaint. The parser evaluates the Next list based on the patient selection and branches to node #2200 (Column 20, lines 29 – 36), which provide said augmenting means is further defined as a selection option mechanism.

- 19. Regarding dependent claims 5 and 6, lift teaches that in situations where the MDATA system 100 cannot determine with sufficient certainty what is causing a particular problem (no diagnosis) or in a situation where a diagnosis is available but additional information is desirable, e.g., to determine a trend, a re-enter flag may be set by the system 100. At a decision state 520, the computer 102 determines if re-enter criteria are met for the current algorithm and patient situation. If so, the computer sets the re-enter flag at state 522 for this problem so a subsequent telephone consultation by the patient will allow for additional information to be added to the patient record by the system in full knowledge of the previous call. This additional information may yield a better diagnosis (Column 42, lines 21 – 34), which provide said augmenting means includes at least one of data addition means for adding information and data substituting means for substituting information and said augmenting means includes an elicitation database for intelligently suggesting at least one of more accurate conclusions, alternative conclusions, and predetermined criteria to support the conclusions.
- 20. **Regarding dependent claim 7**, lliff teaches that "Current Procedural Terminology" (CPT-4) codes are available to describe and bill third party payers for telephone consultations. They are a listing of the descriptive terms and identifying

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codes for reporting medical services and procedures. CPT-4 codes are the most widely accepted nomenclature for reporting physician services to insurance companies (Column 25, lines 39 – 45), which provide that said augmenting means includes eliciting conclusions selected from the group consisting essentially of medical payment codes, billing codes, treatment codes, and service codes.

- 21. Regarding dependent claim 8, lliff teaches that each patient has their own associated symbol table. A portion of a symbol table 212 is shown in FIG. 5b. The symbol table is loaded at run time with memory variables that hold patient specific data (age, sex, and items from medical history) and algorithm specific data. The items in the symbol table can be flagged for storage to the patient's medical history (Column 18, lines 5 11), which provide said augmenting means includes analysis of predetermined criteria input wherein the criteria includes phrases, words, numbers and symbols relating to the conclusions.
- 22. Regarding dependent claim 9, lliff teaches that as another embodiment of the MDATA system, a person desiring medical advice and having access to a personal computer (PC) loads a program into the PC to produce a stand-alone medical diagnostic and treatment advice (SA-MDATA) system (Column 4, lines 18 22), which provide for being utilized on a device selected from the group consisting essentially of hand-held devices, portable computers, desktop computers, wireless devices, web-based technology systems, touch screen devices, typing devices, and electronic devices.

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23. Regarding dependent claim 10, lliff teaches that before the MDATA system stores any information, the system verifies its accuracy. To accomplish this task, "confirmation loops" are used. Any piece of information that will become a part of the patient's medical record is sent through a confirmation loop where the system asks the patient to verify the accuracy of the information that the system has collected. The confirmation loop enables the system to verify new patient information and make corrections before it enters this information into the patient's medical record (Column 13, lines 55 – 64), which provide accuracy confirming means for confirming the accuracy of previously entered information.

- 24. Regarding dependent claim 11, lliff teaches that in addition, the MDATA system 100 is currently using optical character recognition technology to digitize its medical database. Then, using indexing techniques, the MDATA system 100 is able to search for and retrieve any information desired. For example, the system can search for the character string "headache" and retrieve any amount of surrounding text or graphic information (Column 60, lines 9 15), which provide searching means for locating words and phrases.

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with a unique node (Column 17, line 65 – Column 18, line 4), which provide *linking* means for linking to a listing and description of predetermined criteria.

- 26. Regarding dependent claim 13, lliff teaches that the user responds to questions and directions displayed on the computer screen via a computer input device, such as a keyboard or mouse (Column 4, lines 23 26), which provide free-text entry means for entering text into said system.
- 27. Regarding dependent claim 14, lliff teaches that the computer 102 prompts the patient for the patient ID (identification) number (PIN) that is assigned during the registration process. The patient registration process 252 will be described in conjunction with FIGS. 9a and 9b. Proceeding to a decision state 361, the computer 102 determines whether the PIN is valid (Column 29, line 14 20), which provide security means for restricting access to said system.
- 28. **Regarding independent claim 15**, the claim incorporates substantially similar subject matter as claim 1, and is rejected along the same rationale.
- 29. Regarding dependent claim 16, lliff teaches that as another embodiment of the MDATA system, a person desiring medical advice and having access to a personal computer (PC) loads a program into the PC to produce a stand-alone medical diagnostic and treatment advice (SA-MDATA) system (Column 4, lines 18 22), which provide accessible through communication systems selected from the group consisting essentially of the Internet, Intranet, Extranet, and electronically.
- 30. **Regarding dependent claim 17**, the claim incorporates substantially similar subject matter as claim 4, and is rejected along the same rationale.

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31. **Regarding dependent claim 18**, the claim incorporates substantially similar subject matter as claim 5, and is rejected along the same rationale.

- 32. **Regarding dependent claim 19**, the claim incorporates substantially similar subject matter as claim 6, and is rejected along the same rationale.
- 33. **Regarding dependent claim 20**, the claim incorporates substantially similar subject matter as claim 7, and is rejected along the same rationale.
- 34. **Regarding dependent claim 21**, the claim incorporates substantially similar subject matter as claim 8, and is rejected along the same rationale.
- 35. **Regarding dependent claim 22**, the claim incorporates substantially similar subject matter as claim 10, and is rejected along the same rationale.
- 36. **Regarding dependent claim 23**, the claim incorporates substantially similar subject matter as claim 14, and is rejected along the same rationale.
- 37. **Regarding dependent claim 24**, the claim incorporates substantially similar subject matter as claim 11, and is rejected along the same rationale.
- 38. **Regarding dependent claim 25**, the claim incorporates substantially similar subject matter as claim 12, and is rejected along the same rationale.
- 39. **Regarding dependent claim 26**, the claim incorporates substantially similar subject matter as claim 13, and is rejected along the same rationale.
- 40. **Regarding independent claim 51**, the claim incorporates substantially similar subject matter as claim 1, and is rejected along the same rationale.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan Hillery whose telephone number is (571) 272-4091. The examiner can normally be reached on M - F, 10:30 a.m. - 7:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph H. Feild can be reached on (571) 272-4090. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUPERVISORY PATENT EXAMINER

NH